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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/113,561	08/25/1993	THOMAS R. ADAMS	DEKA055	3079

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ROBERT E. HANSON
FULBRIGHT & JAWORSKI, LLP
600 CONGRESS AVENUE
SUITE 2400
AUSTIN, TX 78701

EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/13/2004

57

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/113,561

Applicant(s)

ADAMS ET AL.

Examiner

David T. Fox

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/9/96;9/26/96;8/15/00;8/24/00.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4, 67 and 68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4, 67 and 68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 August 1993 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 24, 24, 5, 50 and 54.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1638.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendments and arguments filed 15 August 2000 have overcome all rejections of record. In response to Applicant's withdrawal of appeal filed 15 August 2000 and the Board dismissal of the appeal of 24 August 2000, the following non-final Office action is issued. The amendments filed 9 May 1996, 26 September 1996 and 15 August 2000 have been entered. Claims 2-4 and 67-68 are pending and examined.

The petition under 37 CFR 1.48(b) of 03 January 1995 to change inventorship has been GRANTED, as set forth on page 2 of the Office action mailed 17 April 1995.

The claimed subject matter of maize plants transformed with a gene encoding a grain composition trait was first contemplated in the instant application, on pages 41-47, which recited a list of enzymes allegedly involved in grain composition. None of the parent applications list any enzyme involved in grain composition. Accordingly, the effective filing date for maize transformed with the instantly claimed genes is the filing date of the instant application, namely 25 August 1993. The effective filing date for maize transformation in general is 17 April 1990, the filing date of the earliest parent application which disclosed this feature.

Claims 2-4 and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 68 is indefinite for depending upon cancelled claim 1. It appears that claim 67 was intended. Dependent claims 2-4 are included in this rejection.

Claims 2-4 and 67-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to fertile maize plants transformed with a laundry list of genes encoding a laundry list of enzymes involved in grain composition, i.e. fatty acid content and carbohydrate content; wherein the enzymes and genes are from any source, including plant, bacteria, fungi or animals; wherein the enzymes and genes are of any sequence; and wherein many of the genes are in either sense or antisense orientation.

In contrast, the specification does not provide guidance for the isolation or identification of even a single gene from a single source and of a single sequence which encodes any of the enzymes recited in claims 67-68 and dependents. The specification does not provide guidance for plant transformation with any fatty acid synthesis or carbohydrate synthesis gene, in either sense or antisense orientation. The specification merely lists enzymes thought to be involved in fatty acid synthesis or carbohydrate synthesis on pages 41-47, and suggests plant transformation therewith.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a

precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the claim breadth and lack of guidance as discussed above, wherein the specification fails to provide any written description of even a single species, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in

possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Claims 2-4 and 67-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to fertile maize plants transformed with a laundry list of genes encoding a laundry list of enzymes involved in grain composition, i.e. fatty acid content and carbohydrate content; wherein the enzymes and genes are from any source, including plant, bacteria, fungi or animals; wherein the enzymes and genes are of any sequence; and wherein many of the genes are in either sense or antisense

orientation. The claims also specify that the presence of the transgene confers a distinguishable phenotype on the transformed maize plants and seeds.

In contrast, the specification does not provide guidance for the isolation or identification of even a single gene from a single source and of a single sequence which encodes any of the enzymes recited in claims 67-68 and dependents. The specification does not provide guidance for plant transformation with any fatty acid synthesis or carbohydrate synthesis gene, in either sense or antisense orientation. The specification does not demonstrate that any putatively transformed plant possessing the claimed transgenes would exhibit an altered phenotype. The specification merely lists enzymes thought to be involved in fatty acid synthesis or carbohydrate synthesis on pages 41-47, and suggests plant transformation therewith.

The process of isolating starch synthesis genes or modifying starch accumulation in transgenic plants is particularly unpredictable. See Kossmann et al (1995; Progress in Biotechnology, Volume 10), who teach the lack of influence of antisense potato starch accumulation genes on branching or phosphate content of starch (page 275, third through fifth full paragraphs), the difficulty inherent in isolating individual starch synthesis enzymes or their corresponding genes (paragraph bridging pages 275 and 276), and the lack of correlation between reduction of branching enzyme gene activity and branching of starch in transgenic plants (see, e.g., page 277, penultimate paragraph).

The process of altering fatty acid composition in transformed plants is also unpredictable. Post-Beittenmiller (1989) et al teach that transformation with an acyl

carrier protein gene failed to produce any detectable phenotypic change in fatty acid synthesis or accumulation, even though acyl carrier protein is involved in fatty acid biosynthesis in native plants (see, e.g., page 889, Abstract). Stephanopoulos et al (1993) teach that plant transformation for the modification of fatty acid accumulation has not been generally successful, that few eukaryotic organisms have had their metabolic pathways successfully altered, and that such alteration of metabolic pathways and accumulated metabolic products is limited by lack of knowledge of the rate limiting step, the existence of multiple rate limiting steps, and the evolved resistance of metabolic pathways to change even when a single enzyme or single step is altered (see, e.g., page 392, Abstract; paragraph bridging pages 392 and 393; page 393, paragraph bridging the columns; page 394, paragraph bridging the columns and the bottom two paragraphs of column 2; page 395, top paragraph; page 396, column 1, bottom paragraph).

Given the claim breadth, unpredictability and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify and isolate a multitude of non-exemplified grain composition genes from a multitude of non-exemplified sources, to transform maize plants therewith in sense or antisense orientation, and to evaluate and obtain transformed maize plants with altered phenotype following said transformation.

Claims 2-4 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Tomes et al (U.S. Patent 5,886,244 or U.S. Patent 6,258,999, each effectively filed 10 June 1988), further in view of each of Shewmaker et al (U.S. 5,349,123 effectively filed 21 December 1990) or Barry et al (U.S. 5,498,830 effectively filed 18 June 1990).

The claims are drawn to a particle-bombardment-mediated method for producing fertile maize plants and seeds transformed with a gene encoding a starch grain composition trait including ADP glucose pyrophosphorylase, wherein said ADP glucose pyrophosphorylase gene confers a phenotype in transformed plant tissue which distinguishes it from untransformed maize plants.

Tomes et al teach and claim a particle bombardment-mediated method for the production of fertile transgenic maize plants containing a foreign transgene of interest encoding a desirable agronomic trait and selectable herbicide or antibiotic resistance marker genes including a kanamycin resistance gene or a hygromycin resistance gene, wherein both inbreds and hybrids were transformed. See U.S. Patent 5,886,244, column 1, lines 35-45; column 1, line 60-column 2, line 22; column 2, line 57-column 3, line 3; column 6, line 43-column 12, line 60; and claims 1-11. See also claims 1-40 of U.S. Patent 6,258,999 where transformed fertile maize plants are explicitly claimed.

Tomes et al do not teach corn transformation with an ADP glucose pyrophosphorylase gene for increased starch production.

Shewmaker et al teach the construction of plant transformation vectors comprising an ADP glucose phosphorylase *glgC* gene from *E. coli* ligated to a signal sequence for proper transport to the starch-containing amyloplast, the use of the selectable kanamycin resistance gene, and the increased starch production in cells transformed with *E. coli* genes encoding proteins involved in glycogen and starch metabolism such as the *glgC* and *glgA* genes; and suggest the use of seed-specific promoters and the particle-bombardment-mediated transformation of cereals including

corn for an increase in starch synthesis (see, e.g., Figure 3; column 2, lines 3-25 and 46-49; column 3, lines 1-7 and 29-37; column 10, lines 20-28 and column 16, line 26-column 17, line 4).

Barry et al teach the construction of plant transformation vectors comprising an ADP glucose phosphorylase *glgC* gene from *E. coli* ligated to a signal sequence for proper transport to the starch-containing amyloplast, the presence of a selectable marker gene such as the kanamycin resistance gene, the transformation of maize cells via particle bombardment, the use of maize seed-specific promoters such as the zein promoter, and the utility of the process for obtaining cereal seeds with increased starch levels (see, e.g., Figures 21-22; column 2, lines 1-36 and 55-63; column 5, lines 44-56; column 5, line 66-column 6, line 9; and column 37, lines 53-67).

It would have been obvious to one of ordinary skill in the art to utilize the method for obtaining fertile maize plants comprising a gene of interest and a selectable antibiotic resistance marker gene including the hygromycin resistance gene, as taught and claimed by each Tomes et al patent, and to modify that method by incorporating the ADP glucose pyrophosphorylase gene ligated to appropriate seed-specific promoters and signal sequences for the increased production of starch in corn seeds, as taught and suggested by each of Shewmaker et al and Barry et al. The use of seed propagation from fertile maize plants is widely practiced in the art.

Claim 68 is deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest maize transformation with a sucrose synthase gene.

No claim is allowed.

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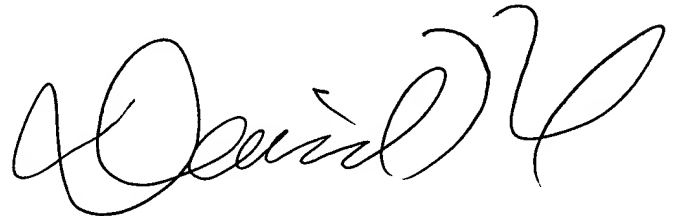
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

May 11, 2004

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638

A handwritten signature in black ink, appearing to read "David T. Fox", written in a cursive style.